K100995

510(k) Summary
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7-Apr-10

JUN 2 5 2010

Shikani Medical LLC
689 Pyle Road
Forest Hill, MD 21050

Tel – 410-638-1066
Fax – 410-638-1413

Official Contact: Fred DeBaugh - Partner

Proprietary or Trade Name: Shikani speaking valve

Common/Usual Name: Speaking valve

Classification Name: Tube tracheostomy and tube cuff
JOH – 21 CFR 868.5800

Predicate Devices: Pilling Weck (Teleflex) – Shikani-French speaking valve
K982128

Device Description
The Shikani speaking valve consists of a plastic housing with a captured ball that acts as a check valve. Once attached to the tracheostomy tube connector the speaking valve allows the patient to inhale through the tracheostomy tube and exhale across the vocal cords which facilitates speech or phonation.

Indications for Use
To allow airflow over the vocal cords for speaking function. To be used with a standard 15 mm connection on tracheostomy tubes.

Environment of Use

Home, Hospital, Sub-acute Institutions

Performance Testing

Performance testing which was used in the original submission K982128 was:

- Resistance to flow – comparison to predicates demonstrated that the values were equivalent
- Weight – comparison to predicates demonstrated that the values were equivalent
- Biocompatibility according to ISO 10993 was performed and the materials passed

The proposed device meeting and passed all the performance testing as outlined above and thus demonstrated substantial equivalence.

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Features	Predicate K982128 Shikani-French	Proposed Shikani speaking valve (Shikani-French 15)
Intended use	To allow airflow over the vocal cords for speaking function	To allow airflow over the vocal cords for speaking function
Comment	The intended use is identical as the devices are the same	
Indications for use	To allow airflow over the vocal cords for speaking function. To be used only as an attachment to CL Jackson improved trachea tubes	To allow airflow over the vocal cords for speaking function. To be used with a standard 15 mm connection on tracheostomy tubes
Comment	The indications for use are identical with exception that K982128 was for the model which was only to be attached to the CL Jackson tracheostomy tube. Teleflex later introduced another model for use with standard tracheostomy tubes with 15 mm connections. This model was considered a line extension and not requiring a modification to the existing 510(k). As the proposed Shikani speaking valve is the same as the Shikani-French 15 speaking valve, the indications for use are identical.	
Environment of Use	Hospital, Sub-acute Institutions, Home	Hospital, Sub-acute Institutions, Home
Comment	Identical	
Patient Population	Tracheostomy patients	Tracheostomy patients
Comment	K982128 did not specify patient population, but we intend for the patient population to be the same.	
Contraindications	Not for use in-line with a ventilator	Not for use with an inflated tracheostomy tube cuff Not for use with an unconscious patient Not for use with patients without the ability to exhale air around the tracheostomy tube and cuff and through the upper airway.
Comment	Teleflex did not include contraindications in K982128, but a review of other speaking valves suggests that the proposed contraindications would be appropriate to add to our labeling. These contraindications are not new and do not come as a result of any new risk analysis, but are felt to be informative only.	

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Features	Predicate K982128 Shikani-French	Proposed Shikani speaking valve (Shikani-French 15)
Standard 22 / 15 mm connections Per ISO 5356-1	Yes – it can connect to the breathing circuit but has a fitting only to be attached to the CL Jackson tracheostomy tubes	Yes – standard fitting to connect to the breathing circuit and to a standard tracheostomy tube with a 15mm connector.
Comment	Identical as they are the same device	
Weight (gm)	32 gm	32 gm
Comment	Identical as they are the same device	
Valve type	Ball	Ball
Comment	Identical as they are the same device	
Attachment to tube	Attachment clip	Attachment clip
Comment		Identical as they are the same device
Pressure drop	1.3 cm H_2O @ 30 lpm 2.0 cm H_2O @ 40 lpm	1.3 cm H_2O @ 30 lpm 2.0 cm H_2O @ 40 lpm
Comment	Identical as they are the same device	
Materials	Housing - Celcon C251-A Acetyl Copolymer Ball - Nylon 6/6 Grade 2 Pin – 316 Stainless steel	Housing - Celcon C251-A Acetyl Copolymer Ball - Nylon 6/6 Grade 2 Pin – 316 Stainless steel
Comment	Identical as they are the same device	

Differences between Other Legally Marketed Predicate Devices

There are no differences between the proposed device and the predicate device as they are the same device.

Form Approved: OMB No. 0910-0120; Expiration Date: 5/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

ISO 5356-1:2004, Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 1-62		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance:

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described in the standard; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Conformance was not tested as the device is unchanged, but this standard is referenced.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Shikani Medical, LLC
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K100995
Trade/Device Name: Shikani Speaking Valve
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: April 7, 2010
Received: April 9, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K100995 (To be assigned)

Device Name: Shikani speaking valve

Indications for Use:

To allow airflow over the vocal cords for speaking function. To be used with a standard 15 mm connection on tracheostomy tubes.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** __ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100995